

Message Text

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ORIGIN HEW-06

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DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VB
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
EUR/WE:BMCKINLEY(INFO)
EUR/WE:JDOBBINS(INFO)

-----121160 151919Z /50

R 151556Z MAR 78
FM SECSTATE WASHDC
TO AMEMBASSY ROME
AMEMBASSY BERN
AMEMBASSY PARIS
AMEMBASSY STOCKHOLM
AMEMBASSY OSLO
AMEMBASSY BONN

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E.O. 11652:N/A

TAGS: OTRA, OGEN, ETRD, EIND, TBIO, IT, SZ, FR, SW, NO, GW

SUBJECT: FDA REPRESENTATIVES PROVIDING TECHNICAL AND CONSUL-
TATIVE ASSISTANCE TO EUROPEAN BIOLOGICALS/MANUFACTURERS

1. FDA ADVISES THAT HOROLD BAER, PHD. AND MICHAEL F. BARILE, PHD., DIVISION OF BACTERIAL PRODUCTS, BUREAU OF BIOLOGICS, WILL BE IN EUROPE APRIL 21-MAY 12, 1978.
2. DR.'S BAER AND BARILE WILL VISIT FIVE (5) BIOLOGICAL MANUFACTURERS AS PART OF AN ANNUAL INSPECTION IN ACCORDANCE WITH PHS ACT 351 (C) AND TO DETERMINE IF THE FIRMS FACILITIES AND OPERATIONS ARE IN ACCORDANCE WITH CURRENT GOOD
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PAGE 02 STATE 066329

MANUFACTURING PRACTICES AND WILL REPORT ANY SIGNIFICANT DEVIATIONS WHICH WOULD HAVE AN ADVERSE EFFECT UPON THE SAFETY AND/OR EFFICACY OF SUCH BIOLOGICALS IMPORTED INTO THE UNITED STATES.

3. ITINERARY AS FOLLOWS:
APRIL 20, 1978 - ARRIVE ROME, ITALY, TRAVEL TO SIENA, ITALY

APRIL 24-25 - VISIT SCLAVO
APRIL 26 - TRAVEL SIENA TO MILAN
APRIL 27 - TRAVEL MILAN, ITALY TO BERNE, SWITZERLAND
APRIL 28 - VISIT SWISS SERUM INSTITUTE
APRIL B9 - TRAVEL BERNE, SWITZERLAND TO LYON, FRANCE

MAY 1-2 - VISIT INSTITUT MERIEUX
MAY 3 - TRAVEL LYON, FRANCE TO COPENHAGEN, DENMARK
MAY 8 - VISIT PHARMACIA, ENGELHOLM, SWEDEN
MAY 9 - TRAVEL TO UPPSALA SWEDEN VIA STOCKHOLM, SWEDEN

4. DR. BAER:

MAY 10 - TRAVEL STOCKHOLM, SWEDEN TO OSLO, NORWAY
MAY 11 - CONFER WITH DOCTOR OLA WESBY CONCERNING RESULTS
OBTAINED BY FDA PANEL ON REVIEW OF ALLERGENIC EXTRACTS
MAY 12 - DEPART OSLO, NORWAY FOR WASHINGTON, DC

5. DR. BARILE:

MAY 10 - TRAVEL STOCKHOLM, SWEDEN TO HANOVER, WEST GERMANY
MAY 12 - CONSULT WITH DOCTOR HELGA KIRCHHOFF AT INSTITUT
FUR MIKROBIOLOGIE IN HANOVER TO DISCUSS MYCOPLASMA VACCINE
PROGRAM
MAY 13 - TRAVEL HANOVER, WEST GERMANY TO WASHINGTON, DC

6. ASSISTANCE OF EMBASSY WILL NOT BE REQUIRED. VANCE

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Message Attributes

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